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IN THE
Supreme Court of the United States

AVENTIS PHARMA S.A.
AND AVENTIS PHARMACEUTICALS INC.,
Petitioners,

v.

AMPHASTAR PHARMACEUTICALS, INC.
AND TEVA PHARMACEUTICALS USA, INC.,
Respondents.

On Petition For A Writ Of Certiorari
To The United States Court Of Appeals
For The Federal Circuit

**BRIEF FOR *AMICI CURIAE* OLE NILSSEN
AND GEO FOUNDATION LTD. IN
SUPPORT OF PETITIONERS**

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INTEREST OF *AMICI CURIAE*¹

Amici are Ole Nilssen, a visionary inventor, and Geo Foundation Ltd. ("Geo"), to which he transferred patent licensing rights in 2000. During a career spanning 50 years, Nilssen has contributed greatly to the development of energy-saving devices, while assembling a portfolio of over 240 patents. These include the first successful configuration of the compact fluorescent light bulb or "CFL," the often spiral-shaped bulb that can be screwed into a regular socket and is fast replacing the traditional incandescent light bulb. CFLs use about 75% less energy than standard incandescent bulbs, last years longer, and thus will save the public hundreds of billions of dollars.

Amici are strongly interested in the outcome of this petition, because 16 of Nilssen's patents have been declared unenforceable based on rulings similar to those at issue here, including application of what amounts to a negligence standard to an assessment of intent. For example, a district court found inequitable conduct with respect to one of Nilssen's CFL patents (the '270 patent (patent number 5,233,270)), worth hundreds of millions dollars, solely because he underpaid maintenance fees on the

¹ The parties have consented to the filing of this brief. Counsel for all parties have been given notice of the *amici curiae's* intention to file this brief as required by Supreme Court Rule 37.2(a). No counsel for a party authored this brief in whole or in part, and no counsel or party made a monetary contribution intended to fund the preparation of this brief. No person other than *amici curiae* made a monetary contribution to its preparation or submission.

patent by \$5,000 after it had issued, underpayments that had no possible effect on patentability. It found this underpayment to be intentional even though there was no affirmative evidence of intent and Nilssen offered an explanation the Federal Circuit acknowledged was not unreasonable as to why he believed his payments were in accord with the law. *Nilssen v. Osram Sylvania, Inc.*, 504 F.3d 1223, 1231-32, 1235 (Fed. Cir. 2007), *cert. denied*, 128 S. Ct. 2938 (2008). The Federal Circuit explained, however, that “inadvertence can carry an applicant only so far.” *Id.* at 1235. The court appeared to recognize that it was effectively applying what amounted to a negligence standard, explaining that Nilssen, who had prosecuted his patents pro se, “thought he didn’t need professional patent help. The result of this case, regrettably, proves that he was wrong.” *Id.*

The issues in the *Aventis* petition before this Court are similar to those raised in *Nilssen* and many other cases. Indeed, Judge Rader’s dissent in *Aventis* cited the *Nilssen* ruling on underpaid maintenance fees as a leading example of recent decisions that have “too often emphasized materiality almost to the exclusion of the lofty intent requirement for inequitable conduct, . . . [m]erging intent and materiality at levels far below” what the law ostensibly requires. Pet. App. 33a. And the Senate Judiciary Committee has cited the *Nilssen* case as an example of decisions applying the materiality requirement in a manner that improperly underemphasizes the question whether the claimed omission or misstatement was important

to the Patent and Trademark Office's ("PTO's") decision to issue the patent. S. Rep. No. 110-259, at 33 n.155 (2008). Clearly, Nilssen's omissions were not important to patentability, as Nilssen informed the PTO of the omissions, and the PTO still issued reexamination certificates for five of the patents held unenforceable, and otherwise confirmed the patentability of numerous claims from several other of those patents before vacating the reexamination proceedings as effectively moot in light of the unenforceability determinations.

The effects of the decision in Nilssen's own case have already been devastating. The initial decision resulted in the unenforceability of patents worth hundreds of millions of dollars, as well as an attorneys' fees award of more than \$5 million dollars. *Nilssen v. Osram Sylvania, Inc.*, 523 F.3d 1352 (Fed. Cir. 2008). And it has led to decisions by other courts finding other Nilssen patents unenforceable on collateral estoppel grounds, because, for example, the same maintenance fee issue existed for those patents. The consequences of a decision on the present petition, establishing whether there will be new standards for inequitable conduct determinations, will impact Nilssen's remaining enforceable patents, as well as his continuing inventive efforts.

SUMMARY OF ARGUMENT

The question presented in the petition is of critical importance to inventors well beyond Aventis, as well as to the patent system as a whole. The Federal Circuit has strayed far from the genesis of

the inequitable conduct doctrine in this Court's jurisprudence and has created a doctrine under which extremely valuable patents can be rendered unenforceable based on conduct that is at most negligent. This disproportionate sanction decreases the incentive for invention and encourages defendants to make inequitable conduct claims in all patent litigation, dramatically increasing the cost of that litigation.

As the Federal Circuit has explained, "[t]he inequitable conduct doctrine, a judicially created doctrine, was borne out of a series of Supreme Court cases in which the Court refused to enforce patents where the patentees had engaged in *fraud* in order to procure those patents." *Digital Control Inc. v. Charles Mach. Works*, 437 F.3d 1309, 1315 (Fed. Cir. 2006) (emphasis added) (citations omitted); *see also Star Scientific, Inc v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1365-66 (Fed.Cir. 2008) (noting that the penalty for inequitable conduct "was originally applied only in cases of 'fraud on the Patent Office'" (citations omitted), *petition for cert. filed*, 77 U.S.L.W. 3437 (2009) (No. 08-918). For many years, the inequitable conduct doctrine was applied very narrowly and played only a minor role in patent litigation. But in recent years, the doctrine has evolved to a point where it bears little resemblance to its origins, and raising such claims has become a routine part of how lawyers defend against infringement allegations. Patentees are now often deprived of valuable property rights for conduct that in no way helped them to obtain those rights, based on very weak evidence of intent, and even where the

value of the lost patent rights is vastly disproportionate to the misconduct at issue. This case cements those trends.

The decision at issue here underscores that the Federal Circuit has eviscerated the requirement of deceptive intent, by failing to require any evidence of deceptive intent beyond the evidence of materiality. *See, e.g.*, Pet. App. 33a (Rader, J., dissenting) (noting judicial trend of "exclusion of any analysis of the lofty intent requirement for inequitable conduct"). Here, as in many other cases, the Federal Circuit affirmed a district court decision inferring that an omission was intentionally deceptive based on its finding that the omitted information was highly material and its disbelief of the explanation for the omission. It did not require any separate evidence of intent. That result turns the intent requirement into a negligence standard.

The consequences of that error have been exacerbated by a second, interrelated error. While common law fraud requires materiality and reliance, the Federal Circuit has relaxed the requirement that misstatements and omissions during patent prosecution be "material" to patentability — *i.e.*, be important factors in the outcome of the prosecution. In each of the seminal Supreme Court decisions bearing on the issue, the "highly reprehensible" conduct giving rise to the "unclean hands" determination had an "immediate and necessary relation" to core issues of patentability (*i.e.*, patentees were not "punish[ed] for extraneous transgressions"). *Keystone Driller Co. v. Gen. Excavator Co.*, 290 U.S. 240, 245 (1933). Now,

however, the Federal Circuit permits the nullification of valuable patent rights on grounds that did not and could not have affected patentability, grounds that the PTO itself would not deem to be "material" under its narrower standard of materiality. *See, e.g., Digital Control Inc.*, 437 F.3d at 1316 ("the PTO's recent adoption of an arguably narrower standard of materiality does not supplant or replace our case law"). Since materiality is then used to infer intent, the weakening of the standard for materiality in turn weakens the standard for intent, as was the case here.

Third, the Federal Circuit has effectively prescribed a finding of unenforceability as the automatic sanction for a finding of inequitable conduct without any meaningful balancing to determine whether the misconduct identified justifies rendering patents unenforceable and worthless. This often results in a punishment that is grossly disproportionate to the offending conduct. *See, e.g., Nilssen*, 504 F.3d at 1233 (finding no abuse of discretion in decision to hold unenforceable patents worth hundreds of millions of dollars on grounds that post-issuance maintenance fees were underpaid by a few thousand dollars). That is precisely what happened here, where petitioner was deprived of valuable patent rights with only weak evidence of materiality and little or no evidence of intent. This is a far cry from this Court's cases where the penalty for a finding of unclean hands was dismissal only of the existing cause of action, *see Precision Instrument Manufacturing Co. v. Automotive Maintenance Machinery Co.*, 324 U.S.

806, 819 (1945), and, then, only in a case of actual fraud.

The evolution of this jurisprudence has the effect of depriving patentees of rights to valid and otherwise patentable subject matter. It also inundates the judicial system with "an absolute plague" of litigation over whether the most minor procedural missteps constitute "inequitable conduct." *Burlington Indus., Inc. v. Dayco Corp.*, 849 F.2d 1418, 1422 (Fed. Cir. 1988). As Judge Rader put it in his dissent in the decision below:

Although designed to facilitate USPTO examination, inequitable conduct has taken on a new life as a litigation tactic. The allegation of inequitable conduct opens new avenues of discovery; impugns the integrity of patentee, its counsel, and the patent itself; excludes the prosecuting attorney from trial participation (other than as a witness); and even offers the trial court a way to dispose of a case without the rigors of claim construction and other complex patent doctrines.

Pet. App. 31a.

Equally bad, the overinclusiveness of the doctrine has had the perverse effect of frustrating the very patent examination process it was designed to protect. Fearful of inequitable conduct charges, patent applicants now engage in the practice of over-disclosure, thereby flooding the PTO with irrelevant information. *See, e.g., American Bar Association Section of Intellectual Property, A Section White Paper: Agenda for 21st Century Patent Reform* 18

(2007). Thus, a doctrine designed by this court over six decades ago as a means to promote equity has been transformed into an instrument for producing profound injustice, and in so doing, contravenes the constitutional mandate “[t]o promote the Progress of ... useful Arts.” U.S. Const. art. I, § 8, cl. 8.

ARGUMENT

I. The Federal Circuit Has Eviscerated the Important Requirement of Deceptive Intent

This Court should grant review to require affirmative evidence of deceptive intent, distinct from evidence of materiality. Under the doctrine of unclean hands, which this Court invoked in establishing the doctrine of inequitable conduct, deliberate deception is required. *See A.H. Emery Co. v. Marcan Prods. Corp.*, 389 F.2d 11, 17 n.4 (2d Cir. 1968); *Eresch v. Braecklein*, 133 F.2d 12, 14 (10th Cir. 1943). The Federal Circuit’s decision here confirms that it has effectively eradicated this requirement and adopted a “should have known” standard that equates to negligence.

The inequitable-conduct doctrine grew out of three cases from this Court, each of which involved fraudulent conduct: *Precision Instrument Manufacturing Co. v. Automotive Maintenance Machinery Co.*, 324 U.S. 806 (1945); *Hazel-Atlas Glass Co. v. Hartford-Empire Co.*, 322 U.S. 238 (1944); and *Keystone Driller Co. v. General Excavator Co.*, 290 U.S. 240 (1933). Fraud, of course, requires deliberate deception, which existed in each of these cases. *Precision Instrument*, for example, was a case where the “history of the patents and

contracts in issue [were] steeped in perjury and undisclosed knowledge of perjury" and where one of the asserted patents "was admittedly based upon false data which destroyed whatever just claim it might otherwise have had to the status of a patent." *Precision Instruments*, 324 U.S. at 816.

In the 1970s and 1980s, decisions from the regional circuits and then the Federal Circuit began to erode the requirement of deliberate deception and to replace it with a gross negligence standard although there were conflicting decisions on the issue. *See* Pet. at 20-22. By 1988, with the courts applying a weakened deceptive-intent standard, fully 80% of all patent-infringement cases included charges of inequitable conduct. *See* Ad Hoc Committee on Rule 56 and Inequitable Conduct, American Intellectual Property Law Association, *The Doctrine of Inequitable Conduct and the Duty of Candor in Patent Prosecution: Its Current Adverse Impact on the Operation of the United States Patent System*, 16 AIPLA Q.J. 74, 75 (1987). The Federal Circuit recognized that the doctrine had become "an absolute plague" on the patent system, with charges of inequitable conduct in "almost every major patent case." *Burlington Indus., Inc.*, 849 F.2d at 1422. In response, the Federal Circuit, sitting en banc, held in *Kingsdown Medical Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867 (Fed. Cir. 1988), that "intent to deceive" is indeed a requirement in all inequitable-conduct cases and that gross negligence is insufficient. *Id.* at 876.

Nonetheless, as Aventis explains in its petition, after *Kingsdown*, the Federal Circuit continued to

rely on a sliding scale of intent and materiality under which “[t]he more material [a patent applicant’s] omission or misrepresentation, the less intent that must be shown.” Pet. App. 18a. As the Federal Circuit has interpreted this standard, a knowing deception can be presumed from the fact that highly material information was omitted, because he who failed to supply highly material information *should have known* about the information’s materiality. *Praxair, Inc. v. ATMI, Inc.*, 543 F.3d 1306, 1315 (Fed. Cir. 2008); *Brasseler, U.S.A. I, L.P. v. Stryker Sales Corp.*, 267 F.3d 1370, 1375-76 (2001). Moreover, the Federal Circuit has concluded that “[a] party charging inequitable conduct may make a *prima facie* case by showing an unexplained violation of the duty of candor,” shifting the burden to the inventor to explain the omission. *Paragon Podiatry Lab., Inc. v. KLM Labs., Inc.*, 984 F.2d 1182, 1192 (Fed. Cir. 1993).

The Federal Circuit has applied the “should have known” and burden-shifting standards in many cases even as, in other cases, panels have recognized that discredited explanations of good faith cannot not serve as affirmative evidence of deceptive intent. *Star Scientific*, 537 F.3d at 1368 (“RJR cannot carry its burden [of proving deceptive intent] simply because Star failed to prove a credible alternative explanation.”). This inconsistency only adds to the inequity of the cases in which intent is inferred. It also sows confusion, creating the need for guidance that the *en banc* Federal Circuit has been unwilling to provide.

The present case exemplifies the problem. In it, the district court found the omission of information by one scientist in an affidavit to be highly material and then inferred deceptive intent largely based on the “should have known standard,” placing the burden on the patentee to explain to the court the basis for the omission. The Federal Circuit affirmed.

Other cases are similar. In *Nilssen*, for example, the district court found Nilssen’s failure to inform the PTO of a lawsuit he had filed against Motorola to be highly material as a matter of law under Section 2001.06(c) of the nonbinding Manual of Patent Examining Procedure (“MPEP”) even though it was undisputed that nothing happened in *Motorola* that could have affected the pending applications. *Nilssen v. Osram Sylvania, Inc.*, 440 F. Supp. 2d 884, 909-10 (N.D. Ill. 2006), *aff’d*, 504 F.3d 1223 (Fed. Cir. 2007), *cert. denied*, 128 S. Ct. 2938 (2008). The district court then inferred intent from its finding of high materiality and its disbelief of Nilssen’s explanations for the nondisclosure. *Id.* It did so even though there was no direct evidence that Nilssen intended to deceive the PTO by omitting reference to *Motorola*, Nilssen’s testimony that he had no knowledge of MPEP § 2001.06(c) was plausible, and Nilssen had no motive to withhold information that was not relevant to patentability. The Federal Circuit affirmed the intent finding without explanation, while acknowledging that Nilssen’s “[f]ailure to cite the Motorola litigation to the PTO [Patent and Trademark Office] may have been an oversight.” *Nilssen*, 504 F.3d at 1235.

The fundamental problem with *Aventis* and *Nilssen* -- that the Federal Circuit does not require evidence of deceptive intent separate from materiality -- extends even to cases where there is not high materiality. See, e.g., *Hoffman-La Roche v. Promega Corp.*, 323 F.3d 1354, 1366-67 (Fed. Cir. 2003) (upholding findings of intent in case of low materiality based on inventor's failure to explain his error); *Novo Nordisk Pharm., Inc. v. Bio-Technology Gen. Corp.*, 424 F.3d 1347, 1361-62 (Fed. Cir. 2005) (imputing knowledge of regulatory provision to inventor). In *Nilssen*, for example, the Federal Circuit deferred to findings that Nilssen had deliberately underpaid maintenance fees on his patents, including the '270 CFL patent, even though neither the district court nor the Federal Circuit deemed Nilssen's underpayment of maintenance fees to be "highly" material, and the findings were predicated on little more than the district judge's unexplained disbelief of the inventor's plausible claims of unintentional error. 504 F.3d at 1230-33, 1235. The decision was particularly extreme given that: (1) it would have been totally irrational for Nilssen to put more than \$100,000,000 in royalties at risk by underpaying \$5,000 in maintenance fees for the '270 patent, (2) Nilssen had repeatedly made the correct amount of fees on other patents, suggesting he made such payments when he thought they were due, and (3) the Federal Circuit acknowledged that Nilssen's explanation as to why he paid lower fees was not unreasonable. *Id.* at 1227-28, 1230-33, 1235. The *Nilssen* decision was subsequently cited by Judge Rader in his *Aventis* dissent as an example of recent cases that have "too often emphasized

materiality almost to the exclusion of any analysis of the lofty intent requirement for inequitable conduct, . . . [m]erging intent and materiality at levels far below" what the law ostensibly requires. Pet. App. 35a.

To be sure, the evidence of intent need not always be direct. But *some* affirmative evidence, direct or circumstantial, is required. A finding of materiality is not itself evidence of intent. Nor is disbelief of a witness's own explanations. See, e.g., *Bose Corp. v. Consumers Union of U.S., Inc.*, 466 U.S. 485, 512 (1984) ("[D]iscredited testimony is not considered a sufficient basis for drawing a contrary conclusion."); *Moore v. Chesapeake & Ohio Ry. Co.*, 340 U.S. 573, 576 (1951) ("[D]isbelief of the [witness's] testimony would not supply a want of proof.").

As exemplified by the instant decision, the law now purports to require intent but in fact requires little more than negligence. See, e.g., James E. Hanft & Stacey S. Kerns, *The Return of the Inequitable Conduct Plague: When "I Did Not Know" Unexpectedly Becomes "You Should Have Known,"* INTELL. PROP. & TECH. L.J., Feb. 2007, at 5 ("The theme of these decisions is that, once materiality of information is found, the Federal Circuit is far more likely to infer an intent to deceive . . . than it has in the past. The trend is away from the stricter standard of *Kingsdown*, which required proof of *scienter* of the charged party, and more toward a strict liability standard."); Charles M. McMahon, *Intent to Commit Fraud on the USPTO: Is Mere Negligence Once Again Inequitable?*, 27 AIPLA Q.J. 49, 75-76 (1999) (noting renewed use of

"should have known" standard that provides an incentive to dig through plaintiff's files for a shot at rendering the patent unenforceable). The result of the relaxed intent standard is that patent cases are almost inevitably turned in part into inequitable conduct cases, increasing the cost and decreasing the predictability of patent litigation and diminishing incentives to invest in innovative technologies.

II. The Decision Below is Predicated on a Relaxed Standard of Materiality That Exacerbates the Effects of the Federal Circuit's Evisceration of the Intent Requirement

Because the sliding scale test ties the requirements for proof of intent to materiality, the intent requirement has been further watered down through a weakening of the materiality requirements. Under the Federal Circuit's test, which it applied in the case below, Pet. App. 51a, information can be material even if it does not directly affect patentability and even if the agency to which the information is submitted, the PTO, would not consider the information material.

When this Court created the doctrine of inequitable conduct in cases involving "deliberately planned and carefully executed scheme[s] to defraud," *Hazel-Atlas*, 322 U.S. at 245, its goal was "to safeguard the public in the first instance against fraudulent patent monopolies," against patents that issued *as a result of* fraud. *Precision Instruments*, 324 U.S. at 818. Where misrepresentations "were not the basis for [the patent] or essentially material to its issue," this Court concluded the

misrepresentations should not result in unenforceability. *Corona Cord Tire Co. v. Dovan Chem. Corp.*, 276 U.S. 358, 373-74 (1928). This is consistent with requirements of common law fraud that, in addition to intentional deception, there also be both materiality and reliance.

In keeping with both these requirements, some courts adopted a "but for" standard for materiality under which a misrepresentation or omission was only deemed material if the patent would not have issued "but for" the misrepresentation or omission. *See Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1362 (Fed. Cir. 1984) (citing cases). But the Federal Circuit strayed from that requirement, holding that the information withheld does not have to be objectively determinative of patentability. In keeping with the then-extant standard at the PTO, the Federal Circuit adopted a standard under which information material where there is "[1] a substantial likelihood that [2] a reasonable examiner [3] would consider it important [4] in deciding whether to allow the application to issue as a patent," regardless of whether it actually affected patentability. *Id.*

The PTO has subsequently narrowed its view of materiality somewhat, but the Federal Circuit has not. *See Digital Control, Inc.*, 437 F.3d at 1315-16. In contrast to the Federal Circuit, the PTO considers information material only if it establishes "a *prima facie* case of unpatentability" of a claim, which the PTO defines as information that "*compels* a conclusion that a claim is unpatentable." 37 C.F.R.

§ 1.56(b) (2004) (emphasis added).² By applying a standard broader than the PTO's standard, the Federal Circuit has undermined the PTO's expressed purpose for its rule: to "provide greater clarity and hopefully minimize the burden of litigation on the question of inequitable conduct." Duty of Disclosure, 57 FED. REG. 2021, 2023 (Jan. 17, 1992). It has also ignored this Court's admonishments that (1) judges should be cautious in policing information submitted to an administrative agency (here the PTO) that has the competence and expertise to police its own procedures, see *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350-51 (2001); *ABF Freight Sys., Inc. v. NLRB*, 510 U.S. 317, 323-25 (1994); *Vermont Yankee Nuclear Power Corp. v. Natural Res. Def. Council, Inc.*, 435 U.S. 519, 524-25 (1978), and (2) that, when agencies act under delegated authority to police their own decisionmaking processes, those decisions are entitled to deference. See *National Cable & Telecomm. Ass'n v. Brand X Internet Servs.*, 545 U.S. 967, 982-83 (2005) (agency action after judicial action nonetheless entitled to deference); *City of Milwaukee v. Illinois*, 451 U.S. 304, 315-19 (1981) (agency establishment of remedy pursuant to congressional scheme displaces equitable remedy).

In recent years, the Federal Circuit has further expanded the concept of materiality, departing even

² Information is also considered material if it "refutes, or is inconsistent with, a position the applicant takes in: (i) Opposing an argument of unpatentability relied on by the [Patent] Office, or (ii) Asserting an argument of patentability." *Id.*

from its own express standards requiring that information at least be *potentially* relevant to patentability. For example, in *Nilssen*, the Federal Circuit held that failure to pay maintenance fees was material even though the underpayments had no possible effect on issuance of the patents, since they were made years after the patent was issued. *Nilssen*, 504 F.3d at 1231-32. See also *Ulead Sys., Inc. v. Lex Computer & Mgmt. Corp.*, 351 F.3d 1139, 1146 (Fed. Cir. 2003). It also upheld an unenforceability ruling based on *Nilssen*'s failure to disclose to the PTO the existence of separate litigation, the *Motorola* litigation, even though it was undisputed that nothing had occurred in the litigation that was even minimally relevant to patentability. *Nilssen*, 504 F.3d at 1233-34. Many other cases have reached similar results. See, e.g., *Ferring B.V. v. Barr Labs., Inc.*, 437 F.3d 1181, 1187-90 (Fed. Cir. 2006) (holding patent unenforceable for failure to identify declarant's interest); *Hoffman-La Roche, Inc.*, 323 F.3d at 1372-81 (Newman, J., dissenting) (describing findings of materiality with respect to characterization of an experiment even though there was no dispute the experiment would work). For reasons such as these, the Senate Judiciary Committee cited *Nilssen* and other cases as examples of recent Federal Circuit decisions applying the materiality requirement in a manner that improperly underemphasizes the question whether the claimed omission or misstatement was important to the PTO's decision to issue the patent. S. Rep. No. 110-259, at 33 n.155.

The decision below is predicated on the Federal Circuit's diluted materiality standard. The Federal Circuit upheld the district court's findings that omission of certain dosage information was material based on its own standard for materiality, rather than the PTO's, or this Court's. Pet. App. 100a. Under its own standard, it affirmed findings that the omission was not just material, but highly material. Pet. App. 46a. And that finding of high materiality was a predicate of the finding of intent. Pet. App. 51a. As Judge Rader explained, high materiality was found even though: (1) Aventis corrected its mistake, and (2) the PTO reissued the patent after it had all of the correct information before it, showing that the omitted information did not establish a *prima facie* case, let alone a determinative case, of unpatentability. Pet. App. 37a. Thus, information that was not even material under the PTO's *prima facie* test, or under a *but for* test, became the basis of a finding of high materiality from which intent was inferred.

The *Aventis* case thus exemplifies the importance of a watered down notion of materiality that pervades the Federal Circuit's jurisprudence. When the watered down notion of materiality is combined with a sliding scale under which intent can be inferred from materiality, inequitable conduct can easily be inferred from small errors that did not, and in many cases could not have, affected the outcome of the patent prosecution. The result is an inequitable-conduct doctrine divorced from the goal of protecting the public from issuance of unwarranted patents.

III. The Automatic Sanction of Unenforceability Is Disproportionate

In perhaps the most harmful departure from the equitable roots of the inequitable conduct doctrine, the Federal Circuit has turned a finding of inequitable conduct into an automatic sanction of unenforceability without any weighing of the equities. As is fitting for a doctrine rooted in equity, when this Court first concluded that inequitable conduct could result in dismissal of a patent enforcement suit, it did so recognizing that there would be a "wide range to the equity court's [discretion]," taking into account private and public interests, the type of misconduct, the degree of culpability, and whether the misconduct "impregnated" the "entire cause of action and justified dismissal." *Precision Instrument*, 324 U.S. at 815, 819. But the Federal Circuit has never affirmed findings of materiality and intent and gone on to reverse a finding of unenforceability. In the case below, it did not even engage in any balancing to determine whether the misconduct identified justifies rendering patents unenforceable and worthless.

Weighing of the equities is critical given the "deeply rooted" principle that the "punishment should fit the crime." *BMW of N. Am., Inc. v. Gore*, 517 U.S. 559, 575 n.24 (1996) (quoting *Solem v. Helm*, 463 U.S. 277, 284 (1983)). Applying that principle, this Court has articulated a number of equitable factors in evaluating the acceptability of a punishment: the reprehensibility of the offense, the

harm caused, and the magnitude of sanctions for similar misconduct. This Court has applied such factors in assessing punitive damages under the Due Process Clause, *see, e.g., BMW, Inc. of N. Am.*, 517 U.S. at 574-85; punishments under the Excessive Fines Clause, *see, e.g., United States v. Bajakajian*, 524 U.S. 321, 334 (1998); and sentences under the Cruel and Unusual Punishments Clause, *see, e.g., Solem v. Helm*, 463 U.S. 277, 284 (1983).

Courts have applied similar principles in other areas of intellectual property law. For example, courts can refuse to enforce copyrights based on fraud upon the agency, but do so “only rarely, when the [right-holder’s] transgression is of serious proportions.” 4 MELVILLE B. NIMMER & DAVID NIMMER, *NIMMER ON COPYRIGHT* § 13.09[B], at 13-310 (2006). Yet courts considering inequitable conduct do not apply these principles, as they should do, in evaluating enforceability of patents. *See* Donald S. Chisum, *Patent Law and the Presumption of Moral Regularity: A Critical Review of Recent Federal Circuit Decisions on Inequitable Conduct and Willful Infringement*, 69 J. PAT. & TRADEMARK OFF. SOC’Y 27, 32 (1987) (“[A] court should temper the sanctions for inequitable conduct to conform to the seriousness of the offense and the relationship between the conduct and the commercially significant claims in the patent.”). To the contrary, once the crime has been found, the death penalty has become automatic.

Application of the harshest penalty has a second problem as well. This Court has made clear that imposition of a penalty of unenforceability of a patent (rather than dismissal of the existing suit) is

not appropriate in a private lawsuit even for the most serious forms of inequitable conduct. It has recognized on repeated occasions that only the government may ask the judiciary to "vacate" a patent; "*such a remedy is not available in infringement proceedings*," *Hazel-Atlas*, 322 U.S. at 251 (citing *United States v. American Bell Telephone Co.*, 128 U.S. 315 (1888)); *see also Mowry v. Whitney*, 81 U.S. 434, 441 (1871). It follows that the remedy of unenforceability is also precluded, since its effect is not materially different than a decision to vacate. And, as noted by Aventis in its petition, this Court has otherwise counseled against private rights of action for fraud on administrative agencies. *Buckman Co.*, 531 U.S. at 351.

The Federal Circuit's imposition of a penalty beyond the bounds permitted by this Court, as well as its failure to articulate relevant factors such as proportionality to tailor a sanction to the facts, leads directly to decisions like this one. Here, an important patent to a life-saving drug worth over \$2 billion in annual sales has been nullified on grounds of conduct falling well short of "the most extreme cases of fraud and deception." Pet. App. 31a (Rader, J., dissenting).

Aventis is far from alone. In *Nilssen*, the Federal Circuit upheld the District Court's decision that the '270 CFL patent was unenforceable solely because Nilssen underpaid maintenance fees by \$5,000, an underpayment that had no possible effect on issuance of the patent, and for which Nilssen offered an explanation that the Federal Circuit determined was not unreasonable. *Nilssen*, 504 F.3d at 1235.

The consequences to Nilssen of the unenforceability determination was the loss of a patent worth more than \$100 million — a ratio of at least 20,000 to 1. Compare, e.g., *State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408, 425 (2003) (noting that “few [punitive] awards exceeding a single-digit ratio . . . will satisfy due process”).

In *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388 (2006), the Court rejected the Federal Circuit’s categorical rule requiring issuance of an injunction in almost all circumstances once infringement has been found. *Id.* at 391-94. This Court held that equity requires case-by-case balancing. *Id.* A similar correction is glaringly needed here, where the Federal Circuit’s departures from the original principles of *Precision Instrument* mean that (1) gargantuan penalties may be imposed as an automatic sanction for minimal misconduct and (2) inequitable-conduct claims are being asserted routinely, threatening arbitrary deprivation of valuable property rights. It is time for this Court to intervene and reaffirm that the inequitable-conduct doctrine does not provide “a remedy for every mistake, blunder, or fault in the patent procurement process,” but rather should be restricted “to only the most extreme cases of fraud and deception.” Pet. App. 31-33a (Rader, J., dissenting). Cf. *Exxon Shipping Co. v. Baker*, 128 S. Ct. 2605, 2629 (2008) (“[W]e are acting here in the position of a common law court of last review, faced with a perceived defect in a common law remedy.”).

IV. The Court Should Grant Review Because the Evolution of the Inequitable Conduct Doctrine Has Sweeping Negative Consequences

As the standards for a finding of unenforceability have weakened in cases such as *Aventis, Nilssen* and many others, the “absolute plague” of inequitable-conduct charges has returned. See Lynn C. Tyler, *Kingsdown Fifteen Years Later: What Does It Take to Prove Inequitable Conduct?*, 13 FED. CIR. B.J. 267, 276, 283 (2003). Given the complexities of the patent process and the scientific process, it almost always will be possible to dredge up errors and claim they are intentional. See *Hoffman-La Roche*, 323 F.3d at 1381 (Newman, J., dissenting). In a recent four-year period, the percentage of cases with inequitable-conduct rulings nearly doubled, see Kevin Mack, *Reforming Inequitable Conduct To Improve Patent Quality: Cleansing Unclean Hands*, 21 BERKELEY TECH. L.J. 147, 155 (2006), leading Judge Newman to denounce the epidemic of “[l]itigation-induced assaults on the conduct of science and scientists, by aggressive advocates intent on destruction of reputation and property for private gain.” *Hoffman-La Roche*, 323 F.3d at 1372 (Newman, J., dissenting).

The vast expansion of the doctrine — with no basis in congressional action or Patent Office regulation or the decisions of this Court — has had far-reaching ramifications. The enforceability of otherwise valid patents is regularly challenged in litigation, frustrating the incentive goals of the patent system, adversely affecting decisions to invest in innovative technologies, and escalating patent-

litigation costs. The National Academy of Sciences and the National Academy of Engineering have recommended abolishing the inequitable-conduct doctrine “to reduce the cost and increase the predictability of patent infringement litigation outcomes.” National Research Council, *A Patent System for the 21st Century* 82-83 (2004); *see id.* at 121-23; *see also* Paul M. Janicke, *Do We Really Need So Many Mental and Emotional States in United States Patent Law?*, 8 TEX. INTELL. PROP. L.J. 279, 292 (2000) (noting that no other country has adopted an inequitable-conduct defense because the doctrine “truly applies only where the patent is valid but was improperly procured,” and that the “number of these instances is bound to be small and does not seem to justify putting every patentee through the cost and jeopardy of a trial on inequitable conduct”). Whether or not the judicially-created inequitable conduct doctrine should be abolished, there scarcely can be doubt that dramatic reform is long overdue.

CONCLUSION

The Writ of Certiorari should be granted.

Respectfully submitted,

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